K080966

510(K) SUMMARY

AUG - 6 2008

SUBMITTER: AOTI Ltd..

DATE: 31 March 2008

COMMON NAME: Topical Oxygen Therapy System

PROPRIETARY NAME: Hyper-Box Topical Wound Oxygen System

CONTACT: Robbie Walsh
VP Quality Assurance and Regulatory Affairs
AOTI Ltd,
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Parkmore Business Park West,
Galway,
Ireland.
Tel: + 353 87 2355402
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CLASSIFICATION: Class III per 21 CFR 878.5650

PREDICATE DEVICES:

AOTI Ltd. is claiming substantial equivalence to the following predicate medical devices:

Predicate Device	**510(k) Number**	**Classification**
Advanced Hyperbaric Technologies Inc. Topical Hyperbaric Oxygen Extremity Chamber	N/A (Pre-Amendment)	Class III per 21 CFR 878.5650
Vascular One, Inc VX-400 Topical Hyperbaric Oxygen Chamber	K022028	Class III per 21 CFR 878.5650
GWR Medical O_2 Boot device	K971507	Class III per 21 CFR 878.5650
Metro Medical Manufacturing HEC 1000 Topical Oxygen Chamber for Extremities	K020466	Class III per 21 CFR 878.5650

A Device Description:

The Hyper-Box Topical Wound Oxygen System is a non-invasive device intended to allow the application of topical oxygen at slightly above atmospheric (hyperbaric) pressure to wounds and ulcers of the extremities.

B Intended Use:

The Hyper-Box Topical Wound Oxygen System is intended to be used for the treatment of open acute or chronic wounds, such as;

- skin ulcerations due to diabetes, venous stasis, post surgical infections and gangrenous lesions
- decubitus ulcers
- amputations/infected stumps
- skin grafts
- burns
- frostbite

C Substantial Equivalence

The Hyper-Box Topical Wound Oxygen System is substantially equivalent to other legally marketed medical devices with the same intended use and similar technological features. The predicate devices described within this submission consist of;

- Advanced Hyperbaric Technologies Inc. Topical Hyperbaric Oxygen Extremity Chamber device (pre-amendment device).
- Vascular One, Inc VX-400 Topical Hyperbaric Oxygen Chamber (K022028)
- GWR Medical O_2 Boot device (K971507)
- Metro Medical Manufacturing HEC 1000 Topical Oxygen Chamber for Extremities (K020466)

The materials and design of the Hyper-Box Topical Wound Oxygen System are similar to those of the predicate devices. The technical characteristics of this device do not introduce new questions regarding safety or effectiveness. Furthermore, the labeling associated with the Hyper-Box Topical Wound Oxygen System provides similar information as the predicate devices.

Information provided in the 510(k) submission supports the determination of substantial equivalence. Software design and development, (including verification and validation testing, test and software quality procedures) was conducted using FDA's Guidance for the Content of Premarket Submissions for Software contained in medical devices, dated May 11 2005, as a guidance and per internal company requirements. The Hyper-Box Topical Wound Oxygen System design and testing are also compliant with various voluntary, international standards including: EN60601-1:1990, EN 60601-1-2:1993, CAN/CSA C22.2 No. 601-1M90:1994, UL 2601-1:1994 and 93/42/EEC Medical Device Directive.

The combined testing and analysis of results provides assurance that the device meets its specifications and is safe and effective for its intended use.

In summary AOTI Ltd. has demonstrated the Hyper-Box Topical Wound Oxygen System to be safe and effective. This device is considered to be substantially equivalent to currently marketed devices which have been previously cleared by FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 2008

AOTI, Ltd.
% Mr. Robbie Walsh
Quality Assurance & Regulatory
Affairs
Qualtech House
Parkmore Business Park West
Galway, Ireland

Re: K080966
Trade/Device Name: Hyper-Box Topical Wound Oxygen System
Regulation Number: 21 CFR 878.5650
Regulation Name: Topical oxygen chamber for extremeties
Regulatory Class: III
Product Code: KPJ
Dated: June 30, 2008
Received: July 3, 2008

Dear Mr. Walsh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080966

Indications for Use

510(k) Number:

Device Name: Hyper-Box Topical Wound Oxygen System

Indications for Use:

The AOTI Hyper-Box Topical Wound Oxygen System is intended to be used for the treatment of open acute or chronic wounds, such as;

- skin ulcerations due to diabetes, venous stasis, post surgical infections and gangrenous lesions
- decubitus ulcers
- amputations/infected stumps
- skin grafts
- burns
- frostbite

Prescription Use __X___ AND/OR Over-The-Counter-Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhern

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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